

AUG 12 1996

April 26, 1996



K952050

Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center (HFZ-401)
 9200 Corporate Boulevard
 Rockville, Maryland 20850

Attention: To whom it may concern

Subject: Summary of Safety and Effectiveness Information
 for Oak Carolina Examination Gloves.

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Oak Carolina Inc.
 100 Roe Road
 Travelers Rest, S.C. 29690

Oak Carolina examination gloves are made from poly vinyl chloride (vinyl). They are to be marketed under the trade name Sensi-tex. Their intended use is to prevent an interchange of body fluids via the hands of the wearer and the person (patient) being examined. Specifically, they are designed to prevent blood or other body fluids from the hands of the wearer from being transferred to the examinee. Also they are designed to prevent body fluids from the examinee from being transferred to the wearer via the wearer's hands.

This product is donned or placed on the hands. Care should be taken to prevent rips and tears during donning and use.

The specifications for the gloves are as follows:

Style Number	96-160	96-260	96-360	96-460
Size	Small	Medium	Large	X-Large
Width	92±5mm	105±5mm	114±5mm	124 ± 5mm
Length(minimum)	230mm	230mm	230mm	230mm
Tensile(minimum)	1310 PSI	1310 PSI	1310 PSI	1310 PSI
Elongation(minimum)	300%	300%	300%	300%
*Thickness(range)				
Finger	4-6 mils	4-6 mils	4-6 mils	4-6 mils
Palm	9-13 mils	9-13 mils	9-13 mils	9-13 mils

The product meets the physical requirements specified above both before and after accelerated aging at 158±4.5°F.

*Measured per ASTM D5250 Fig. 1

This product when tested in accordance with ASTM D5151-92 meets the 1000 ml water test leak requirements.

This product contains no color or flavor additives. No dusting powder or donning powder is used in the manufacture of this product.

Biocompatibility studies demonstrate that this product is not a primary irritant to the skin.

This product, a vinyl examination glove is substantially equivalent in composition and function to other vinyl examination gloves.

Sincerely,

A handwritten signature in black ink, appearing to read "Greg Dempsey", written in a cursive style.

Greg Dempsey
Quality Assurance Manager